

ingredient set forth in the pending claims. The rejection appears to be based on the Examiner's contention that the Mahjour disclosure as regards fatty acids renders it obvious to use the fatty acids recited in the pending claims in a topical formulation containing 1-isobutyl-1H-imidazo[4,5-c]quinolin-4-amine. The Examiner contends that "the choice of any one particular fatty acid is a matter of choosing from obvious alternatives".

Applicants wish to call the Examiner's attention to the enclosed Affidavit of Stephen M. Berge under 37 CFR §1.132. This affidavit sets forth the results of certain experiments. Formulations were prepared according to Example 13 of the subject application, using one of several fatty acids in a range of concentrations. Linoleic acid, palmitic acid, and stearic acid were used as comparative examples, while isostearic acid and oleic acid were used to exemplify the claimed compositions.

The data in the affidavit show that over a period of 24 hours isostearic acid and oleic acid afford better delivery characteristics than palmitic acid and stearic acid. Indeed stearic acid and palmitic acid are deemed to be unsuitable for use in delivering the drug across the skin. Furthermore, it was observed that the palmitic acid and stearic acid formulations formed relatively hard white pastes that are not optimal for use as topical formulations. As for linoleic acid it appears that this fatty acid exhibits suitable delivery characteristics, and the formulations are not unduly viscous.

The affidavit serves to refute the contention that the selection of fatty acid is a matter of choosing from obvious alternatives. It is true that linoleic acid, which is not recited in the claims, affords a satisfactory formulation. However, even assuming that the teachings of Mahjour are properly taken as indicating that fatty acids as a genus improve transdermal drug delivery characteristics in connection with certain drugs, the data in the affidavit establish that such is not the case as

regards the active ingredient recited in the pending claims: fatty acids as a genus do not afford formulations that are suitable for delivering 1-isobutyl-1H-imidazo[4,5-c]quinolin-4-amine across the skin. Only through Applicants' inventive activity in connection with 1-isobutyl-1H-imidazo[4,5-c]quinolin-4-amine was it found that isostearic and/or oleic acid in combination with the specifically recited active ingredient would afford a suitable formulation for transdermal delivery.

In view of the data set forth in the affidavit, Applicants contend that Claims 1-15 are not rendered unpatentable under 35 USC §103 by Gerster in view of Mahjour.

Claims 1-15 have also been rejected under 35 USC §103 as unpatentable over Gerster in view of Mahjour and further in view of several secondary references. Despite the disclosures of these secondary references as regards various excipients and auxiliary components, Applicants contend that these references do not overcome the showing set forth in the affidavit.

For the reasons set forth above and in view of the enclosed affidavit, Applicants respectfully request reconsideration, withdrawal of the rejections, and allowance of Claims 1-15.

Respectfully submitted,

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Date

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